

REMARKS/ARGUMENTS

Claims 1-7, 9-17, 19, and 21-26 are pending in the present application.

This Amendment is in response to the non-final Office Action mailed December 20, 2010. In the Office Action, the Examiner rejected claims 1, 2, 4, 9-11, 13, 19, 21, and 26 under 35 U.S.C. §102(b); claims 23-25 are rejected under 35 U.S.C. §102(b); claims 3, 6, 7, 14-16, and 22 under 35 U.S.C. §103(a); claims 5, 12, and 17 under 35 U.S.C. §103(a). Reconsideration in light of the remarks made herein is respectfully requested.

Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 2, 4, 9-11, 13, 19, 21, and 26 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,387,607 issued to Gauthier et al. ("Gauthier"); and claims 23-25 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,485,828 issued to Hauser ("Hauser"). Applicant respectfully traverses the rejection and submits that the Examiner has not met the burden of establishing a prima facie case of anticipation.

1. Claims 1, 2, 4, 9-11, 13, 19, 21, and 26:

Gauthier discloses an apparatus for inhalation therapy. A transducer 12 transmits into a body of coupling liquid 15 which is contained in a chamber 16 (Gauthier, col. 3, line 73 – col. 4, line 4; Figure 2). The energy radiated from the transducer 12 to the liquid in the nebulizing chamber 16 causes the liquid to be thrown upward in the nebulizing chamber (Gauthier, col. 5, lines 23-25). An oscillator 14 is initially adjusted to the resonant frequency of the transducer 12 and is then de-tuned to drive the transducer at a frequency above its resonant frequency (Gauthier, col. 6, lines 32-35). An acoustic lens 121 is provided which may comprise a double concave body having a central orifice 122 to allow the circulation of coupling input (Gauthier, col. 7, lines 7-10).

Gauthier does not disclose, either expressly or inherently, at least one of: (1) a first driver element to generate acoustic energy, the first driver element generating acoustic energy in pulses that are of a short duration and low frequency such that a droplet of pharmaceutical product is output from a capillary wave; (2) a first acoustic lens positioned between the first driver element and the capillary wave to focus the acoustic energy generated by the first driver element; and (3)

a delivery system to maintain the pharmaceutical product in a position to receive the acoustic energy from the first acoustic lens and cause ejection of the droplet of pharmaceutical product.

First, Gauthier merely discloses the aerosol output in the vessel 22 is noticeably affected by a change in frequency of the oscillator and thus of the transducer 12 (Gauthier, col. 6, lines 40-42), not a droplet of pharmaceutical product is output from a capillary wave. In the Office Action, the Examiner contends that Gauthier discloses that the frequency of the transducer is adjustable via the oscillator and therefore it appears that the device is capable of performing this function (Office Action, page 2, paragraph 3). Applicant respectfully disagrees. Changing the frequency of the transducer does not necessarily causing a droplet to output from a capillary wave. Gauthier states that this variable frequency only results in a dense fog of nebulized material accompanying a low, broad geyser (Gauthier, col. 6, lines 42-44). According, the variable frequency as taught by Gauthier does not cause forming of a capillary wave.

Second, Gauthier merely discloses the transducer 12 has an electrically conductive coating on its front face (Gauthier, col. 4, lines 8-12), not a driver element generating acoustic energy in pulses that are of a short duration and low frequency. Gauthier merely discloses controlling the operation of the transducer thermostatically in accordance with the attained temperature of the lower vessel 16 which reflects the temperature of the coupling liquid 15 (Gauthier, col. 6, lines 4-7). Gauthier specifically discloses that the transducer should be turned off if the coupling liquid becomes too hot (Gauthier, col. 6, lines 8-11). Accordingly, operating thermostatically only depends on the temperature, not providing pulses that are of short duration and low frequency.

2. Claims 23-25:

Hauser discloses a portable device for micropulverization generated by ultrasound waves. The acoustic fountain phenomenon is accompanied by a mist of microdroplets between 3 and 6 μm in size, created by cavitation or by resonance of the jet's capillary waves (Hauser, col. 1, lines 33-35). Transducer 16 is supplied with a frequency between 1 and 5 megahertz by an electronic circuit 18 running on batteries 20 (Hauser, col. 2, lines 50-52). The ultrasound waves are sent through a cassette 24 containing the liquid for micropulverization to concentrate at one point in the liquid near its surface (Hauser, col. 2, lines 55-58). A jet-shaped 'acoustic fountain' 26 thus forms on the surface of the liquid for micropulverization above the opening 28 of

cassette 24. This jet 26 generates a mist of relatively uniform microdroplets 30 with the smallest diameter between 3 and 6 μm (Hauser, col. 2, lines 58-62). The mist is moved towards the inhaler or diffuser 32 by ventilator 36 (Hauser, col. 2, lines 62-63). At the end of the cassette 24 is a cross membrane 34 made of material with acoustic impedance identical or very close to that of the propagation medium in cell 12 (Hauser, col. 3, lines 35-39).

Hauser does not disclose, either expressly or inherently, at least one of: (4) generating a pulse of acoustic energy, the pulse having a short duration and low frequency such that the pulse of acoustic energy generates capillary waves, at least one capillary wave ejecting at least one droplet of pharmaceutical product; (5) focusing the acoustic energy between the pulse of acoustic energy and the capillary waves; and, (6) positioning the droplet near a human orifice for inhalation into a respiratory system.

First, Hauser merely discloses a mist of microdroplets between 3 and 6 μm in size, created by cavitation or by resonance of the jet's capillary waves (Hauser, col. 1, lines 33-35), not a pulse having a short duration and low frequency such that the pulse of acoustic energy generates capillary waves. Hauser merely discloses microdroplets are created by resonance of the jet's capillary waves, but does not disclose how the jet's capillary waves are created.

Second, Hauser merely discloses a mist of relatively uniform microdroplets 30 with the smallest diameter between 3 and 6 μm (Hauser, col. 2, lines 58-60), not a droplet of pharmaceutical product is output from a capillary wave. The uniform microdroplets 30 are uniform and come from a jet-shaped acoustic fountain. Accordingly, they are not output from a capillary wave.

Third, Hauser merely discloses a reflecting surface 22 of paraboloid or parabolic cylinder type (Hauser, col. 2, lines 54-55), not focusing the acoustic energy between the pulse of acoustic energy and the capillary waves. The reflecting surface 22 merely reflects the ultrasound waves and is positioned horizontally with respect to the transducer 12 (Hauser, FIGURE). It is not placed between the pulse of acoustic energy and the capillary waves.

Fourth, Hauser merely discloses the mist is moved towards the inhaler or diffuser 32 by ventilator 36 (Hauser, col. 2, lines 62-63), not positioning the droplet near a human orifice for inhalation into a respiratory system. The ventilator 36 is located at the diffuser 32. It is used

merely to move the mist toward the inhaler or diffuser 32. Therefore, it is not positioned near a human orifice for inhalation into a respiratory system.

To anticipate a claim, the reference must teach every element of a claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Vergegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). The Examiner bears the burden of presenting at least a prima facie case of anticipation. *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138-139 (Fed. Cir. 1986); *In re Wilder*, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). Only if that burden is met, does the burden of going forward shift to the applicant. *In re King*, 801 F.2d at 1327, 231 USPQ at 138-139; *In re Wilder*, 429 F.2d at 450, 166 USPQ at 548. Once a prima facie case is established and rebuttal evidence is submitted, the ultimate question becomes whether, based on the totality of the record, the Examiner carried his burden of proof by a preponderance. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the Examiner fails to establish a prima facie case, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Since the Examiner failed to show that Gauthier or Hauser teaches or discloses any one of the above elements, the rejection under 35 U.S.C. §102 is improper.

Therefore, Applicant believes that independent claims 1, 23, and 26 and their respective dependent claims are distinguishable over the cited prior art references. Accordingly, Applicant respectfully requests the rejection under 35 U.S.C. §102(b) be withdrawn.

Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 3, 6, 7, 14-16, and 22 under 35 U.S.C. §103(a) as being unpatentable over Gauthier in view of U.S. Patent No. 5,231,426 issued to Sweet ("Sweet"); claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over Gauthier in view of U.S. Patent No. 4,751,530 issued to Elrod ("Elrod"); claim 12 is rejected under 35 U.S.C. §103(a) as being unpatentable over Gauthier in view of U.S. Patent No. 5,372,126 issued to Blau ("Blau"); claim 17 is rejected under 35 U.S.C. §103(a) as being

unpatentable over Gauthier in view of U.S. Patent No. 5,231,426 issued to Sweet ("Sweet") as applied to claim 14 above, and further in view of U.S. Patent No. 6,205,999 issued to Ivri ("Ivri"). Applicant respectfully traverses the rejection and submits that the Examiner has not met the burden of establishing a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP* §2143, p. 2100-126 to 2100-130 (8th Ed., Rev. 5, August 2006). Applicant respectfully submits that there is no suggestion or motivation to combine their teachings, and thus no *prima facie* case of obviousness has been established.

Furthermore, the Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated: "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." MPEP 2141. In *KSR International Co. vs. Teleflex, Inc.*, 127 S.Ct. 1727 (2007) (Kennedy, J.), the Court explained that "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." The Court further required that an explicit analysis for this reason must be made. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR 127 S.Ct.* at 1741, quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). In the instant case, Applicant respectfully submits that there are significant differences between the cited references and the claimed invention and there is no apparent reason to combine the known elements in the manner as claimed, and thus no *prima facie* case of obviousness has been established.

1. Claims 3, 6, 7, 14-16, and 22:

Gauthier is discussed above.

Sweet discloses a nozzleless droplet projection system. At least one electro-acoustic transducer 15 is connected to a head structure 16a having a head cavity 16b (Sweet, col. 2, lines 61-63). Head structure 16a has a smooth perimetrical exterior surface 18 with at least one inscribed acoustic lens 19 (Sweet, col. 2, lines 65-67). The lens shape is preferably spherical, but a Fresnel lens structure may be considered as an alternative (Sweet, col. 3, lines 4-6).

As discussed above, Gauthier does not disclose or render obvious elements (1) – (3) as above. Accordingly, a combination of Gauthier with any other references, including inherency or official notice, in rejecting claims 3, 6, 7, 14-16, and 22 is improper.

Furthermore, Sweet merely discloses one inscribed acoustic lens 19 aligned with each electro-acoustic transducer 15 (Sweet, col. 2, line 67 – col. 3, lines 1), not a first acoustic lens positioned between the first driver element and the capillary wave. Since Sweet does not disclose a capillary wave, the lens, even if it is a Fresnel lens, is not positioned between the first driver element and the capillary wave.

Regarding claim 7, Sweet merely discloses an electronic multiplexer 41 which selectively excites any sequence of electro-acoustic transducers 15 (Sweet, col. 3, lines 45-50), not a multiplexing circuit that directs RF energy from the portable energy source to alternately switch groups of the ejectors on and off, as recited in claim 7. Selectively exciting a sequence of transducers is not the same as alternately switching on and off the ejectors.

2. Claim 5:

Gauthier is discussed above.

Elrod discloses acoustic lens arrays for ink printing. An acoustic printhead 11 comprising an array of precisely positioned spherical acoustic lenses 12a – 12i for launching a plurality of converging acoustic beams 15 into a pool of ink 16 (Elrod, col. 3, lines 16-19). The oscillation of a transducer 23 causes it to generate ultrasonic acoustic waves 24 for collectively or separately illuminating the lenses 121-12i (Elrod, col. 3, lines 37-41).

Gauthier and Elrod, taken alone or in any combination, do not disclose or render obvious, at least one of: (1) – (3) as above in the 102 rejections; and (7) a second acoustic lens to focus the

energy generated by the first driver element and cause ejection of a second droplet of pharmaceutical product, as recited in claim 5.

As discussed above, Gauthier does not disclose at least one of the elements (1) – (3) as recited in claim 1. Accordingly, a combination of Gauthier with any other references in rejecting claim 5, which depends on claim 1, is improper.

Furthermore, Elrod merely discloses converging acoustic beams 15 into a pool of ink 16 (Elrod, col. 3, lines 16-19), not to cause ejection of a second droplet of pharmaceutical product. Acoustic printing involves the use of ink, which is not a pharmaceutical product.

3. Claim 12:

Gauthier is discussed above.

Blau discloses a pulmonary sampling chamber. Ultraviolet light fixtures are place in the sputum induction (SI) room in a manner to sterilize the air and kill aerosolized microorganisms (Blau, col. 1, lines 48-50).

Gauthier and Blau, taken alone or in any combination, do not disclose or render obvious, at least one of: (1) – (3) as above in the 102 rejections, as recited in claim 1 and similarly in independent claim 11; and (8) an ejector head to cover the acoustic lens, the ejector head being sterilized by an ultraviolet radiation source, as recited in claim 12.

As discussed above, Gauthier does not disclose at least one of the elements (1) – (3) as recited in claim 11. Accordingly, a combination of Gauthier with any other references in rejecting claim 12, which depends on claim 11, is improper.

Furthermore, Blau merely discloses using the UV light to sterilize the air kill aerosolized microorganisms (Blau, col. 1, lines 48-50), NOT an ultraviolet source to sterilize the ejector head. Sterilizing the air does not sterilize the ejector head or the acoustic lens.

4. Claim 17:

Gauthier and Sweet are discussed above.

Ivri discloses methods and apparatus for storing chemical compounds in a portable inhaler. An apparatus 10 includes an inhalation flow sensor 24 which detects the inhalation flow produced by the patient when inhaling from mouthpiece 22 (Ivri, col. 7, lines 50-53). Upon detection of the inhalation, sensor 24 sends an electrical signal to an electronic circuit which in

turn sends an alternating voltage to vibrate a piezoelectric member 26 of aerosol generator 22 to aerosolize a liquid (Ivri, col. 7, lines 53-56).

Gauthier, Sweet, and Ivri, taken alone or in any combination, do not disclose or render obvious, at least one of: (1) – (3) as above in the 102 rejections, as recited in claim 1 and similarly in independent claim 14; and (9) a circuit that detects a flow of air going into a patient's lungs and couples the transducer to the portable energy supply when a critical air speed is reached, as recited in claim 17.

As discussed above, Gauthier and Sweet, alone or in combination, do not disclose at least one of the elements (1) – (3) as recited in claim 14. Accordingly, a combination of Gauthier and Sweet with any other references in rejecting claim 17, which depends on claim 14, is improper.

Furthermore, Ivri merely discloses an inhalation flow sensor 24 which detects the inhalation flow (Ivri, col. 7, lines 50-53), not a circuit that detects a flow of air when a critical air speed is reached, as recited in claim 17. Detecting the inhalation flow merely detects if there is a flow. It does not detect the airflow when a critical air speed is reached.

The Examiner failed to establish a prima facie case of obviousness and failed to show there is teaching, suggestion, or motivation to combine the references. When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to: (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). “When determining the patentability of a claimed invention which combined two known elements, ‘the question is whether there is something in the prior art as a whole suggest the desirability, and thus the obviousness, of making the combination.’” *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992), 24 USPQ2d 1040; *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ (BNA) 481, 488 (Fed. Cir. 1984). To defeat patentability based on obviousness, the suggestion to make the new product having the claimed characteristics must come from the prior art, not from the hindsight knowledge of the invention. *Interconnect Planning Corp. v. Feil*, 744 F.2d 1132, 1143, 227 USPQ (BNA) 543,

551 (Fed. Cir. 1985). To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness. In other words, the Examiner must show reasons that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the prior elements from the cited prior references for combination in the manner claimed. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1996), 47 USPQ 2d (BNA) 1453. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or implicitly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973. (Bd.Pat.App.&Inter. 1985). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Furthermore, although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills*, 916 F.2d at 682, 16 USPQ2d at 1432; *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992), 23 USPQ2d 1780.

Moreover, the Examiner failed to establish the factual inquires in the three-pronged test as required by the *Graham* factual inquires. There are significant differences between the cited references and the claimed invention as discussed above. Furthermore, the Examiner has not made an explicit analysis on the apparent reason to combine the known elements in the fashion in the claimed invention. Accordingly, there is no apparent reason to combine the teachings of Gauthier, Sweet, Elrod, Blau, and Ivri in any combination.

In the present invention, the cited references do not expressly or implicitly disclose any of the above elements. In addition, the Examiner failed to present a convincing line of reasoning as to why a combination of Gauthier, Sweet, Elrod, Blau, and Ivri is an obvious application of inhaler using focused acoustic waves, or an explicit analysis on the apparent reason to combine Gauthier, Sweet, Elrod, Blau, and Ivri in the manner as claimed.

Therefore, Applicant believes that independent claims 1, 9, 11, 23, and 26 and their respective dependent claims are distinguishable over the cited prior art references. Accordingly, Applicant respectfully requests the rejection under 35 U.S.C. §103(a) be withdrawn.

Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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